

Applicant earnestly requests that the Examiner consider withdrawing these rejections or withdrawing the finality of these rejections. The Final Office Action cites three new references. The Final Office Action does note reference numbers from the cited references as corresponding to certain claim elements, but does not explain how specific elements within the references are thought to teach the claim elements. If the rejections are maintained, Applicant respectfully requests a description of how the claim elements are taught by the cited references in view of the remarks below.

#### Rejection over House

House describes a syringe that includes a medication-filled vial 12 and a vial adapter 40 that threadably attaches to the vial 12, among many other components. (See, for example, Column 6, lines 58-60 of House stating that the threaded channel 32 of the seal 26 of the vial 12 is engaged with the extending portions 76 and 92 of the vial adapter 40.) As shown by the exploded views of Figures 4-6, after assembly, the vial adapter 40 surrounds a micropore filter 62. The attachment of the vial adapter 40 to the vial 12 holds the micropore filter 62 in place in between them.

In the Office Action, the Examiner argued that the vial 12 was equivalent to the cartridge chamber of the claims. However, claim 1 is related to a medication pump including a cartridge chamber for receiving a medication cartridge, the chamber comprising a first open end for inserting the medication cartridge. In contrast, the vial 12 of House is not described as being for receiving a medication cartridge or including an open end for inserting a medication cartridge. The vial 12 of House contains fluid, not a cartridge. (See column 6, lines 40-43.) Therefore, House does not teach the claimed cartridge chamber for receiving a medication cartridge.

House also does not teach a cartridge chamber with an open end for receiving a medication and ridge. House states, "An identical pair of piston seals 26 are disposed within either end of the vial 12 and are in frictional intimate contact with the inner wall 28 of the glass vial 12 in order to contain the medicament 22 which is in liquid form therebetween." (House, column 3, lines 60-64.) Accordingly, the vial 12 of House is not a cartridge chamber for receiving a medication cartridge and does not have an open end for inserting a medication cartridge, and for these reasons, claim 1 is patentable over House.

The Examiner argues in the Office Action that the micropore filter 62 teaches a pump cap as claimed while the vial adapter 40 teaches a safety cap as claimed. However, these structures in the syringe taught in House do not meet the claim requirements for a pump cap or safety cap according to claim 1. For example, claim 1 specifies that the pump cap is rotationally attached to the open end of the cartridge chamber. However, the micropore filter 62 of House, alleged by the Examiner to be equivalent to the pump cap of claim 1, is not described as rotationally attaching to the vial 12 of House. Instead, the micropore filter 62 is trapped between the vial and the vial adapter 40 when the vial adapter 40 threadably attaches to the piston seal 26 of the vial 12. (House, column 7, lines 1-8). In fact, the micropore filter 62 only contacts the vial 12 via the piercing needle 68 that pierces the piston seal 26 of the vial 12. The micropore filter 62 does not rotationally attach to the vial 12.

In addition, no structure in House satisfies the requirement of the safety cap cover of claim 1. The vial adapter 40 of House is not movable between a first and second state, where in the second state rotation of the vial adapter 40 causes rotation of a pump cap to remove a pump cap from an open end of a cartridge chamber. The vial adapter 40 does not act in this manner with respect to the micropore filter 62 of House. There is no discussion in House of the vial

adapter 40 moving in a second state so that rotation of the vial adapter 40 causes rotation of the micropore filter 62 to remove the micropore filter from the vial 12.

Accordingly, Applicants respectfully submit that claim 1 is clearly patentable over House. House does not describe a cartridge chamber, a pump cap, or a safety cap as described in claim 1.

In addition, the House patent does not teach many of the elements of the dependent claims, including a safety cap cover moving between first and second states by application of a radially inward force as claimed in claim 2, deformation of the safety cap cover as claimed in claim 3, or the provision of gripping structures on either the safety cap cover or the pump cap as specified in claims 4-8. There is no description in House of the vial adapter 40 or the micropore filter 62 having these features. Accordingly, these claims are further patentable over House.

#### Rejection over Maclean

Maclean describes a needle and hub assembly 7 for securing a needle to a syringe 2. Maclean also describes a protective sterile packaging 22 that can be mounted on the needle and hub assembly 7 in order to cover the needle. (Maclean, column 3, lines 4-7). In the Office Action, the Examiner argues that the syringe 2 of Maclean is equivalent to the cartridge chamber of claim 1 and that the needle and hub assembly 7 of Maclean is equivalent to the pump cap. The Examiner also asserts that the protective sterile packaging 22 of Maclean is equivalent to the safety cap of claim 1.

Applicants respectfully submit that Maclean does not teach the elements of claim 1. For example, Maclean does not teach a safety cover capable of moving between a first and second state where in the first state, the rotation of the safety cap cover does not cause rotation of a pump cap that is enclosed by the safety cap cover. In contrast, the protective sterile packaging

22 engages with the needle and hub assembly in a way that does not permit the protective sterile packaging 22 to freely rotate around the needle and hub assembly 7 without causing rotation of the needle and hub assembly 7. The protective sterile packaging 22 includes radially extending lugs 26 that are engageable with grooves 20 on the hub 8. Accordingly, any rotation of the protective sterile packaging 22 would cause rotation of the needle and hub assembly 7.

In addition, Maclean does not teach a pump cap that attaches to an open end of a cartridge chamber, where the cartridge chamber includes a first open end for inserting a medication cartridge. The needle and hub assembly 7 attaches to the end of the syringe having the nozzle portion 4 in Maclean. As seen in Figure 1, the nozzle 4 has a narrower inner diameter than the remainder of the syringe 2. The capsule that fits within the syringe 2 therefore may not be placed within the syringe through the nozzle end of the syringe. Accordingly, the needle and hub assembly 7 attaches to the syringe at the end opposite from the end where a capsule is inserted. Maclean therefore does not teach a pump cap that attaches to an open end of a cartridge chamber where the cartridge chamber includes a first open end for inserting a medication cartridge.

For at least these two reasons, claim 1 is patentable over Maclean.

In addition, many of the dependent claims contain additional features that are not shown in the claim. For example, Maclean does not teach a safety cap cover that is moved between first and second state by applying a radially inward force as claimed in claim 2, or a safety cap cover that deforms as claimed in claim 3, or a safety cap cover with an opening in the end opposite from the end that is attached to a pump cap, as claimed in claim 10. Accordingly, these additional dependent claims are further patentable over Maclean.

#### Rejections over Mavoral

Claims 1-11 and 13 were rejected under 35 U.S.C. § 102(e) as being anticipated by Mayoral. Mayoral relates to a cap for a luer connector. In the Office Action, the Examiner argued that the container C is equivalent to the cartridge chamber of claim 1 and that the open delivery sleeve 42 is equivalent to the pump cap of claim 1. In addition, the Examiner argued that the cap 10 is equivalent to the safety cap of claim 1. Applicants respectfully traverse this rejection and will point out some of the features of claim 1 that are not taught in Mayoral.

The cap 10 of Mayoral is not described in Mayoral as functioning like the safety cap of claim 1. For example, the cap 10 of Mayoral is not taught to have a first and second state where in the second state the cap causes rotation of a pump cap in order to remove a pump cap from the open end of a cartridge chamber. In contrast, the cap 10 of Mayoral is rotated into a sealed position in order to provide a heatset tamper evident seal arrangement for the container C. Mayoral does not describe that rotation of the cap 10 will result in rotation of the open delivery sleeve 42 or removal of the open delivery sleeve 42 from the container C.

In addition, Mayoral does not teach a cartridge chamber for receiving a medication cartridge. The Examiner argued that the container C of Mayoral was equivalent to the cartridge chamber of claim 1. However, Mayoral does not describe the container C as being for receiving a medication cartridge. Instead, Mayoral describes container C as being in flow communication with an open delivery sleeve 42 (Col. 4, lines 60-64), indicating that container C is designed to hold a fluid, not a cartridge.

Another distinction between claim 1 and Mayoral is the fact that Mayoral lacks a pump cap that is rotationally attached to an open end of a cartridge chamber. The Examiner argued that the open delivery sleeve 42 was equivalent to the pump cap of claim 1. The open delivery sleeve 42 of Mayoral is part of the top portion 14 of the closure 12. The closure 12 is never

described in Mayoral as being rotationally attached to the container C. Mayoral simply states that a closure 12 is engaged with a container C to be sealed thereto. (Mayoral, column 4, lines 38-39.) Accordingly, claim 1 is patentable over Mayoral for this additional reason.

In addition to the features of claim 1 discussed above that are not found in Mayoral, the dependent claims include additional features that are not taught in Mayoral. Mayoral does not teach a safety cap cover movable between first and second states by applying a radially inward force as claimed in claim 2, a safety cap cover that deforms as claimed in claim 3, a safety cap cover with an opening in the end opposite from the end that is attached to a pump cap as claimed in claims 10 and 12, or the provision of gripping structures on either a safety cap cover or a pump cap as specified in claims 4-8. There is no description in Mayoral of the cap 10 or the open delivery sleeve 42 or any other structure as having these features. Accordingly, the dependent claims are further patentable over Mayoral.

For at least these reasons, claims 1-11 and 13 are patentable over Mayoral.


#### Conclusion

As discussed above, claims 1-13 each include distinctions over the cited prior art references. Applicants respectfully request withdrawal of the rejections and a Notice of Allowance at an early date. The Examiner is encouraged to contact Applicant's undersigned representative if such contact would be helpful in any way.



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